

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference C04150	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/AU2004/001651	International filing date (<i>day/month/year</i>) 25 November 2004	(Earliest) Priority Date (<i>day/month/year</i>) 26 November 2003
Applicant RESMED LIMITED et al		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II).

3. ☒ **Unity of invention is lacking** (See Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. **5**

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

First invention Claims 1-8, 17-22, 41-48, 53-58, 63-70

Second invention Claims 9-16, 23-40, 49-52, 59-62, 71-85, 90-97, 102-111

Third invention Claims 86-89, 98-101

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Box No. IV Text of the Abstract (Continuation of item 5 of the first sheet)

A method and apparatus for providing ventilatory assistance to a spontaneously breathing patient. An error signal (56) is computed that is the difference between a function of respiratory airflow (54) over a period of time and a target value (52). Using a servo loop, air is delivered to the patient at a pressure that is a function of the error signal, the phase of the current breathing cycle, and a loop gain that varies depending on the magnitude of the error signal. The loop gain increases with the magnitude of the error signal, and the gain is greater for error signals below a ventilation target than for error signals above the ventilation target value. The target value (52) is an alveolar ventilation that takes into account the patient's physiologic dead space.

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A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI IPC A61M, A62B & keywords: target, phase, function and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,532,957 B2 (BERTHON-JONES) 18 March 2003 column 10 lines 54 to 58, column 12 lines 10 to 24, column 3 lines 22 to 32	9-16, 23-40, 49-52, 59-62, 71-79, 82-84, 90-92, 95-97, 102-111
X	WO 2001/019440 A1 (RESMED LTD) 22 March 2001 Abstract	9, 12, 13, 16, 23, 26, 27, 35, 49, 59, 71, 77, 82, 90, 95, 102, 107
A	EP 1 086 716 A2 (SIEMENS) 28 March 2001 Abstract	
A	EP 1 346 743 A1 (WEINMANN MED) 24 September 2003 Abstract	



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"E" earlier application or patent but published on or after the international filing date

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"O" document referring to an oral disclosure, use, exhibition or other means

"&" document member of the same patent family

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search
11 January 2005Date of mailing of the international search report
17 JAN 2005

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

XAVIER GISZ

Telephone No : (02) 6283 2064

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-8, 17-22, 41-48, 53-58, 63-70 are directed to a method for providing ventilatory assistance including the steps of computing a measure of difference between the respiratory airflow and a target value, and delivering air to a patient at a pressure that is a function of the difference measure and the amplitude at a determined phase. It is considered that a function of the difference measure and the amplitude at a determined phase comprises a first "special technical feature".
2. Claims 9-16, 23-40, 49-52, 59-62, 71-85, 90-97, 102-111 are directed to a method of providing ventilatory assistance including the steps of computing a measure of difference between the respiratory airflow and a target value and delivering air at a pressure that is a function of the difference measure. It is considered that a function of the difference measure comprises a second special technical feature.
3. Claims 86-89, 98-101 are directed to a method of providing ventilatory assistance including the steps of determining two patient ventilation measures with different speeds of response, deriving two error signals that are a function of target values, controlling the delivered pressure based on a function of the error signals.

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is a method of providing ventilatory assistance including the step of computing the difference between the ventilation of the patient and a target value. However this concept is not novel in the light of WO 2001/019440. Therefore these claims lack unity *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2004/001651

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	6532957	AU	37625/97	AU	41933/97
		CA	2263126	CA	2266454
		CA	2298553	CA	2478809
		EP	0996358	EP	1005829
		EP	1277435	JP	2001037880
		JP	2002315831	US	6152129
		US	6484719	US	6575163
		US	2002069874	US	2002148466
		US	2004074492	US	2004173212
		WO	9812965	WO	9806449
WO	0119440	AU	74997/00	EP	1229956
EP	1086716	JP	2001112868	US	6739336
EP	1346743	DE	10212497		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Halford & Co. No 1 Market Street SYDNEY NSW 2000		<div style="text-align: center; font-weight: bold; font-size: 1.2em;">PCT</div> <div style="text-align: center; margin-top: 20px;">WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY</div> <div style="text-align: center; margin-top: 20px;">(PCT Rule 43bis.1)</div>
Date of mailing (day/month/year) 17 JAN 2005		
Applicant's or agent's file reference C04150	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/AU2004/001651	International filing date (day/month/year) 25 November 2004	Priority date (day/month/year) 26 November 2003
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ A61M 16/00		
Applicant <div style="text-align: center; font-weight: bold;">RESMED LIMITED et al</div>		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer <div style="font-weight: bold; font-size: 1.1em;">XAVIER GISZ</div> Telephone No. (02) 6283 2064
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-8, 17-22, 41-48, 53-58, 63-70 are directed to a method for providing ventilatory assistance including the steps of computing a measure of difference between the respiratory airflow and a target value, and delivering air to a patient at a pressure that is a function of the difference measure and the amplitude at a determined phase. It is considered that a function of the difference measure and the amplitude at a determined phase comprises a first "special technical feature".
2. Claims 9-16, 23-40, 49-52, 59-62, 71-85, 90-97, 102-111 are directed to a method of providing ventilatory assistance including the steps of computing a measure of difference between the respiratory airflow and a target value and delivering air at a pressure that is a function of the difference measure. It is considered that a function of the difference measure comprises a second special technical feature.
3. Claims 86-89, 98-101 are directed to a method of providing ventilatory assistance including the steps of determining two patient ventilation measures with different speeds of response, deriving two error signals that are a function of target values, controlling the delivered pressure based on a function of the error signals. It is considered that deriving two error signal comprises a third special technical feature.

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is a method of providing ventilatory assistance including the step of computing the difference between the ventilation of the patient and a target value. However this concept is not novel in the light of WO 2001/019440. Therefore these claims lack unity *a posteriori*.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☒ all parts
- ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8, 11, 15-22, 30, 33, 38-48, 51-58, 62-70, 74-76, 79-81, 84-89, 92-94, 97-101, 104, 109	YES
	Claims	9, 10, 12-14, 23-29, 31, 32, 34-37, 49, 50, 59-61, 71-73, 77, 78, 82, 83, 90, 91, 95, 96, 102, 103, 105-108, 110, 111	NO
Inventive step (IS)	Claims	1-8, 17-22, 41-48, 53-58, 63-70, 80-81, 85-89, 93, 94, 98-101	YES
	Claims	9-16, 23-40, 49-52, 59-62, 71-79, 82-84, 90-92, 95-97, 102-111	NO
Industrial applicability (IA)	Claims	1-111	YES
	Claims		NO

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1....US 6,532,957

D2....WO 2001/019440

Novelty (N) Claims 9, 10, 12, 13, 14, 23-29, 31, 32, 34-37, 49, 50, 59-61, 71-73, 77, 78, 82, 83, 90, 91, 95, 96, 102, 103, 105-108, 110, 111

Claims 9, 12, 13, 16, 23, 26, 27, 35, 49, 59, 71, 77, 82, 90, 95, 102, 107: D1 discloses a ventilatory apparatus comprising the steps of a computing the difference between a target and actual ventilation and delivering air to the patient at a pressure that is a function of the difference measure (column 10 lines 54 to 58). The difference measure is a clipped integral of the difference between the target respiratory value (V_{TGT}) and the current respiratory flow (V). The apparatus is controlled by a servo loop (19).

Similarly D2 discloses these features.

Claims 10, 14, 24, 25, 28, 29, 36, 37, 50, 60, 61, 64, 72, 73, 78, 83, 91, 96, 103, 105, 106, 108, 110, 111: D1 discloses the ventilatory assistance is less when the respiratory flows are above the target value than when the respiratory flows is below the target value (column 10 lines 54 to 58 and column 12 lines 10 to 24). The gain increases with the magnitude of the difference.

Claim 31, 32: D1 disclose the phase of the breathing cycle is determined by measuring the respiratory airflow and the rate of change of the airflow (column 3 lines 22 to 32). The determination is made with fuzzy logic rules (Column 9 lines 42 to 69).

Inventive Step (IS) Claims 9-16, 23-40, 49-52, 59-62, 71-79, 82-84, 90-92, 95-97, 102-111

Claims 9, 10, 12, 13, 14, 23-29, 31, 32, 34-37, 49, 50, 59-61, 71-73, 77, 78, 82, 83, 90, 91, 95, 96, 102, 103, 105-108, 110, 111 also lack an inventive step for the reasons given above.

Claims 11, 15, 30, 34, 38, 40, 51, 74, 76, 79, 84, 92, 97, 104, 109: The feature of the target is an alveolar ventilation value taking into account the patient's dead space is not disclosed in the citations, however it would be considered a mere workshop improvement to a PSA in light of D1 to take this value into account and consequently lacks inventive step.

Claim 33, 39, 52, 62, 75: Although the citations do not disclose the pressure of delivered air to be delivered in an amount so as to reduce the error signal, this would be considered a mere workshop improvement to a PSA in light of D1 and consequently lacks inventive step.